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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/620,777 | 07/15/2003 | Roy Curtiss III | 56029/ | 1127 |

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EXAMINER

GANGLE, BRIAN J

| | |
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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/620,777 | Applicant(s) CURTISS ET AL. | |
| | Examiner Brian J. Gangle | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 61-107 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 61-64, 67, 70-73, 76, 8-94, and 104-107 drawn (in part) to microbial cells comprising an essential gene, and methods of making said cells, classified in class 435, subclass 252.3.
- II. Claims 61-66, 70-72, and 82-87, drawn (in part) to microbial cells comprising a lethal gene, and methods of making said cells, classified in class 435, subclass 252.3.
- III. Claims 61-67, 70-73, 76, and 82-87, drawn (in part) to microbial cells comprising an essential gene and a lethal gene, and methods of making said cells, classified in class 435, subclass 252.3.
- IV. Claims 68-69, drawn (in part) to microbial cells comprising two lethal genes, classified in class 435, subclass 252.3.
- V. Claims 68-69, drawn (in part) to microbial cells comprising an essential gene and two lethal genes, classified in class 435, subclass 252.3.
- VI. Claims 74-75, 95-96, and 103, drawn (in part) to microbial cells comprising an essential gene and a regulatory gene which regulates expression of the essential gene, classified in class 435, subclass 252.3.
- VII. Claims 74-75, drawn (in part) to microbial cells comprising a lethal gene, an essential gene, and a regulatory gene which regulates expression of the essential gene, classified in class 435, subclass 252.3.

- VIII. Claims 77 and 97, drawn (in part) to microbial cells comprising an essential gene and a replication gene, classified in class 435, subclass 252.3.
- IX. Claim 77, drawn (in part) to microbial cells comprising a lethal gene and a replication gene, classified in class 435, subclass 252.3.
- X. Claim 77, drawn (in part) to microbial cells comprising an essential gene, a lethal gene, and a replication gene, classified in class 435, subclass 252.3.
- XI. Claims 78-79, drawn (in part) to microbial cells comprising an essential gene, a replication gene, and a regulatory gene which regulates expression of the regulatory gene, classified in class 435, subclass 252.3.
- XII. Claims 78-79, drawn (in part) to microbial cells comprising a lethal gene, a replication gene, and a regulatory gene which regulates expression of the regulatory gene, classified in class 435, subclass 252.3.
- XIII. Claims 78-79, drawn (in part) to microbial cells comprising an essential gene, a lethal gene, a replication gene, and a regulatory gene which regulates expression of the regulatory gene, classified in class 435, subclass 252.3.
- XIV. Claims 80 and 98, drawn (in part) to microbial cells comprising an essential gene and an expression gene, classified in class 435, subclass 252.3.
- XV. Claim 80, drawn (in part) to microbial cells comprising a lethal gene and an expression gene, classified in class 435, subclass 252.3.
- XVI. Claim 80, drawn (in part) to microbial cells comprising an essential gene, a lethal gene, and an expression gene, classified in class 435, subclass 252.3.

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- XVII. Claim 81, drawn (in part) to microbial cells comprising an essential gene and a transfer vector, classified in class 435, subclass 252.3.
- XVIII. Claim 81, drawn (in part) to microbial cells comprising a lethal gene and a transfer vector, classified in class 435, subclass 252.3.
- XIX. Claim 81, drawn (in part) to microbial cells comprising an essential gene, a lethal gene, and a transfer vector, classified in class 435, subclass 252.3.
- XX. Claims 84-87, drawn (in part) to methods of making microbial cells comprising an essential gene, classified in class 435, subclass 69.1.
- XXI. Claims 84-87, drawn (in part) to methods of making microbial cells comprising a lethal gene, classified in class 435, subclass 69.1.
- XXII. Claims 84-87, drawn (in part) to methods of making microbial cells comprising an essential gene and a lethal gene, classified in class 435, subclass 69.1.
- XXIII. Claim 99, drawn to methods of inducing an immune response with a microbial cell comprising an essential gene, classified in class 424, subclass 200.1.
- XXIV. Claims 100-101, drawn to methods of inducing an immune response with a microbial cell comprising an essential gene and an expression gene encoding an antigen, classified in class 424, subclass 200.1.
- XVV. Claim 102, drawn to methods of inducing an immune response with a microbial cell comprising an essential gene, a replication gene, and an expression gene encoding an antigen, classified in class 424, subclass 200.1.

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Election Requirement Applicable to Groups I-XVI

In addition, each Group detailed above reads on patentably distinct microbial cells. Each microbial cell is patentably distinct because they are drawn to organisms with differing biochemical and immunological properties and a further restriction is applied to each Group.

Applicant must further elect, for the group chosen:

Group I – The location of the essential gene (chromosomal or extrachromosomal) and the essential gene (*asd*, *dap*, *dal*, *ddl*, *fab*, *pls*).

Group II – The location of the lethal gene (chromosomal or extrachromosomal).

Group III – The location of both the essential gene and the lethal gene (chromosomal or extrachromosomal).

Group IV – The location of both lethal genes (chromosomal or extrachromosomal).

Group V – The location of the essential gene and both lethal genes (chromosomal or extrachromosomal).

Group VI – The location of the regulatory gene (chromosomal or extrachromosomal).

Group VII – The location of the lethal gene and the regulatory gene (chromosomal or extrachromosomal).

Group VIII – The location of the essential gene (chromosomal or extrachromosomal).

Group IX – The location of the lethal gene (chromosomal or extrachromosomal).

Group X – The location of both the essential gene and the lethal gene (chromosomal or extrachromosomal).

Group XI – The location of the essential gene (chromosomal or extrachromosomal).

Group XII – The location of the lethal gene (chromosomal or extrachromosomal).

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Group XIII – The location of both the essential gene and the lethal gene (chromosomal or extrachromosomal).

Group XIV – The location of the essential gene (chromosomal or extrachromosomal).

Group XV – The location of the lethal gene (chromosomal or extrachromosomal).

Group XVI – The location of both the essential gene and the lethal gene (chromosomal or extrachromosomal).

Applicant is advised that examination will be restricted to only the elected microbial cell and should not be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XIX are related as products. The claims are drawn to microbial cells containing various combinations of essential, lethal, regulatory, and expression genes. The inventions are patentably distinct products because they are made by different methods and because they are physically functionally distinct entities with different biochemical and immunological properties.

Inventions XX-XXV are related as methods. The methods are distinct from one another because they have different goals as evidenced by the preamble (method of making a cell strain; method of inducing an immune response), different method steps (stably introducing an essential gene; stably introducing a lethal gene; stably introducing an essential gene and a lethal gene; administering microbial cells comprising an essential gene; administering microbial cells comprising an essential gene and an expression gene encoding an antigen; administering microbial cells comprising an essential gene, a replication gene, and an expression gene encoding an antigen), and have different final outcomes. Consequently, each method is distinct from the other.

Inventions XX and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case one could make the claimed products by bacterial complementation.

Inventions I and XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the cells of Invention I could be used in a binding assay.

The products of Invention I are separate and distinct from the methods of Inventions XXI-XXII and XXIV-XXV, wherein the products of Invention I may neither be made by nor used in the methods of Inventions XXI-XXII and XXIV-XXV. In the instant case, Invention I is drawn to cells comprising an essential gene, whereas the methods of Inventions XXI-XXII and XXIV-XXV require the use or production of cells comprising a lethal gene; cells comprising an essential gene and a lethal gene; an essential gene and an expression gene encoding an antigen; and cells comprising an essential gene, a replication gene, and an expression gene encoding an antigen.

Inventions XXI and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as

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claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case one could make the claimed products by bacterial complementation.

The products of Invention II are separate and distinct from the methods of Inventions XX and XXII-XXV, wherein the products of Invention II may neither be made by nor used in the methods of Inventions XX and XXII-XXV. In the instant case, Invention II is drawn to cells comprising a lethal gene, whereas the methods of Inventions XX and XXII-XXV require the use or production of cells comprising an essential gene; cells comprising an essential gene and a lethal gene; cells comprising an essential gene and an expression gene encoding an antigen; and cells comprising an essential gene, a replication gene, and an expression gene encoding an antigen.

Inventions XXII and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case one could make the claimed products by bacterial complementation.

The products of Invention III are separate and distinct from the methods of Inventions XX-XXI, and XXIII-XXV, wherein the products of Invention III may neither be made by nor used in the methods of Inventions XX-XXI, and XXIII-XXV. In the instant case, Invention III is drawn to cells comprising a lethal gene, whereas the methods of Inventions XX-XXI, and XXIII-XXV require the use or production of cells comprising an essential gene; cells comprising an essential gene and a lethal gene; cells comprising an essential gene and an expression gene

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encoding an antigen; and cells comprising an essential gene, a replication gene, and an expression gene encoding an antigen.

The products of Inventions IV-XIX are separate and distinct from the methods of Inventions XX-XXV, wherein the products of Inventions IV-XIX may neither be made by nor used in the methods of Inventions XX-XXV. In the instant case, the methods of Inventions XX-XXV require the use of cells comprising an essential gene and an expression gene encoding an antigen; and cells comprising an essential gene, a replication gene, and an expression gene encoding an antigen; however, none of the products of Inventions IV-XIX meet these requirements.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
AU 1645



ROBERT ZEMAN
PATENT EXAMINER